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To: [redacted] GROW
COSMETICS AND MEDICAL DEVICES
Subject: Report - Meeting with EUCOMED - 28.09.2015

Follow Up Flag: Follow up
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Report
- Meeting with EUCOMED -
28/09/2015

Participants:

- [redacted] (GROW/D4)
- [redacted] (EUCOMED)

Main issues discussed and outcomes:

- COM presented a state of play of the ongoing negotiations on the medical device package.
- EUCOMED informed COM that the Presidency/Parliament may consider a two-column text (Council and Parliament positions only) as a basis for discussions in the upcoming trilogue meeting. They are very sceptical towards this possible approach, as they consider

the Commission proposal to be still the most useful/balanced compromise text on many issues and therefore that it should not be taken out from the negotiations table. The COM took duly note of EUCOMED's point.

- EUCOMED introduced the contents of their latest position paper on the ongoing negotiations, in the view of the kick-off of the trilogue. Major concerns of EUCOMED at this stage include:
  - Requirements on clinical evidence/investigations for well-established technologies. EUCOMED considers that the Council text produces a serious gap, by imposing manufacturers to conduct mandatory clinical investigation for well-established high-risk devices in the view of their re-certification, despite

these products have been on the market safely for long time. EUDAMED claims that such requirements may not only be completely inapplicable/inappropriate but would also risk to block the overall system. They referred to Article 10a of Directive 2001/83/EU on medicinal products as possible solution to be taken over in the new medical device legislation.

- Derogation from conformity assessment general scheme for Class IIb implantable devices. EUCOMED is opposed to this "de facto" upgrade of Class IIb devices to Class III, as this is done

without any justification /risk assessment and would therefore seem to be at odd with a principle of risk-based approach. The impact of this provision on the conformity assessment of those products, such as screws, having thousand variants/models, may be huge and likely unmanageable for the overall system.

- EUCOMED mentioned that some issues would deserve further clarity in the text, such as the role of Guidances (such as MEDDEV) under the new legislative framework and the relationship to be established between transparen

cy needs and protection of commercially sensitive information. EUCOMED is of the opinion that clarifying this latter aspect adequately and, most important, establishing a system (Forum/Ombudsman) to prevent abuse/misuse/unduly access to sensitive information is crucial to make sure that the EU regulatory environment remains fit for attracting innovation and research investments.

- EUCOMED indicated that, in the light of the substantial changes to the Commission text made by the Council, it would be appropriate to convene a meeting with all interest stakeholders as a way to assess the feasibility of many measures proposed by the Council.

They will push for this approach when speaking to many MEPs over the next few days/weeks. EUCOMED also informed that, regardless of whether this approach is accepted, they intend to prepare easy-to-read data/graphs and make them available to the parts involved in the negotiations, so that the practical consequences of all options to be discussed are adequately reflected upon. COM pointed out that these data may certainly constitute a significant and interesting input to the upcoming negotiations.